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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,899	05/31/2001	Mark E. Wilson	834460-68474	1013

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	6

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/870,899	Applicant(s) WILSON ET AL.	
	Examiner Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20, 23, 25, 41(in part), 60-62, 65, 67, 69 (in part), and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

Continuation of Disposition of Claims: Claims withdrawn from consideration are 21-22, 24, 26-40, 41 (in part), 42-59, 63-64, 66, 68, and 69 (in part).

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the invention of Group I, Claims 1-18, 41, 60, 69, and 70, in Paper No. 4, submitted January 17, 2002 is acknowledged. The traversal is on the ground(s) that inventions I and II can not be said to be independent and distinct. This is found persuasive as to Groups I and II, drawn to methods of increasing the reproductive performance of a female swine and methods of increasing the number of live births to a female swine. Therefore, the Requirement for Restriction is modified as to Groups I and II. The invention of Group I is herein combined with the invention of Group II. However, Inventions of Groups I-II; and III, VI, V are independent and distinct each from other as discussed in the Requirement for Restriction dated September 25, 2001, and an undue burden on the Office is seen for the search all inventions herein, as discussed in the Requirement for Restriction. Note that the search is not limited to patent files. Note that the search field for a composition is different from the search field for a specified method of employing the same composition.

The requirement is therefore made FINAL.

Therefore, claims 21-22, 24, 26-40, 41 (in part), 42-59, 63-64, 66, 68 and 69 (in part) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20, 25, 41(in part), 60-62, 65, 67, 69 (in part), and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "the reproductive performance" in claims 1, 41 (in part) and 69 (in part) renders claims 1-18, 41 (in part) and 69 (in part) indefinite. The expression "the reproductive performance" is not defined by the claims and specification. Therefore, the scope of claims is indefinite as to "the reproductive performance" encompassed thereby.

The expression "biologically effective amount" in claims 1, 20, 25, 41 (in part), 61-62, 67, 69 (in part) and 70 renders claims 1-20, 25, 41(in part), 60-62, 65, 67, 69 (in part), and 70 indefinite. The expression "biologically effective amount" is not defined by the claims and specification. Therefore, the scope of claims is indefinite as to "biologically effective amount" encompassed thereby.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20, 23, 25, 41(in part), 60-62, 65, 67, 69 (in part), and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stitt (5,110,592, PTO-1449 submitted February 15, 2002) in view of Applicant's admission regarding the prior art in the specification of pages 1-3 and Boudreaux et al. (HY, PTO-1449 submitted February 15, 2002)

Stitt discloses that omega-3 fatty acids such as alpha-linolenic acid, eicosopentenoic acid, and docosohexanoic acid in an edible composition comprising flaxseed to be administered daily is useful in a method for increasing the number of live births to a female animal such as a female swine. Stitt teaches that flaxseed is known to contain omega-3 fatty acids such as alpha-linolenic acid, eicosopentenoic acid, and docosohexanoic acid. See abstract, col.1 line 35-68, col.4 lines 13-17, col.5 line 58 to col.6 line 15, and claims 1-61.

Stitt does not expressly disclose that the sources of same omega-3 fatty acids as the instant claims are not derived from fish oils. Stitt does also not expressly disclose the employment of these omega-3 fatty acids in combination with omega-6 fatty acids in a composition and a method for increasing the reproductive performance such as increasing the number of live births to a female swine. Stitt does not expressly disclose the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to a female swine.

Applicant's admission regarding the prior art in the specification of pages 1-3 teaches the following: the instant omega-3 fatty acids such as eicosopentenoic acid, and docosohexanoic acid and docosapentaenoic acid are well known to be derived from fish oils and marine algae (see page 2 lines 13-14); Omega-6 fatty acids are known to increase the number of live births in animals (see page 2 lines 24-25); Salmon oil is known to be used in animal food (see page 2 lines 26-27); Omega-3 fatty acids in particular are known to be useful to increase female animal fertility (see page 2 lines 29-30); Salmon oil is known to contain both omega-3 fatty acids and omega-6 fatty acids (see page 3 lines 1-3).

Boudreaux et al. discloses that the range of the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to animals is within the instant claim. See abstract and page 236 3rd paragraph of left column.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ omega-3 fatty acids herein which are derived from fish oil in the claimed method for increasing the reproductive performance, to employ these omega-3 fatty acids in combination with omega-6 fatty acids in a composition and the claimed method herein, to optimize the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to a female swine.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ omega-3 fatty acids herein which are derived from fish oil in the claimed method for increasing the reproductive performance, to employ these omega-3 fatty acids in combination with omega-6 fatty acids in a composition and the

claimed method herein, because omega-3 fatty acids herein are known to be useful in an edible composition to be administered daily and in a method for increasing the number of live births to a female swine based on the prior art. Omega-3 fatty acids in particular are known to be useful to increase female animal fertility. Omega-6 fatty acids are also known to increase the number of live births in animals. Moreover, the instant omega-3 fatty acids such as eicosopentenoic acid, and docosohexanoic acid and docosapentaenoic acid are well known to be derived from fish oils and marine algae. Salmon oil is known to contain both omega-3 fatty acids and omega-6 fatty acids. Therefore, one of ordinary skill in the art would have reasonably employed any fish oils and marine algae such as salmon oil as sources of omega-3 fatty acids and omega-6 fatty acids, so long as these fish oils contain omega-3 fatty acids and omega-6 fatty acids. Applicant is further requested to note that the sources of omega-3 fatty acids and/or omega-6 fatty acids are not considered a limitation to a composition comprising omega-3 fatty acids and/or omega-6 fatty acids. Therefore, one of ordinary skill in the art would have reasonably expected that combining omega-3 fatty acids and omega-6 fatty acids known useful for the same purpose i.e., increase female animal fertility, in a composition to be administered would improve the therapeutic effect for increasing the reproductive performance of a female swine such as increasing the number of live births of a female swine.

Since all active composition components herein are known to useful to increase the number of live births in animals, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same

purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Additionally, one of ordinary skill in the art would have been motivated to optimize the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to a female swine because the range of the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to animals are known in the art and the optimization of amounts of active agents to be administered is considered well within the skill of artisan.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. A. Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. A. Jiang, Ph.D.
Patent Examiner, AU 1617
April 12, 2002

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